Report- rGLC Mission Country Support for Updating PMDT Guidelines

Country: Nepal

Dates of Mission: 8-12 April 2019

Authors:

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Acknowledgements:

We hereby extend our gratitude and gratefully acknowledge the support provided by the NTC team specifically Dr Bhim Singh Tinkari (NTC Director), Mr Anil Thapa(Chief Planning) and Dr Naveen Shah(Chief of PMDT) for Leadership and other team members of NTC and NRL team for technical inputs and support and facilitation

We also acknowledge the support and technical inputs from in country NTC partners as their close coordination and great inputs enabled us to update and finalize the 1st draft of guidelines

- Dr Ashesh Dhungana(Clinical fellow of NTC and TWG member)
- Dr Suvesh Kumar shrestha (Save the children)
- Dr Bahabana Shrestha(GENETUP)
- Dr Promod Bhattarai(Damien foundation)
- Mr Gokul Mishra(LSTM country team)

Our greatest gratitude and special thanks to Dr Jos Vandelaer (WR WHO country office, Nepal) and Dr Lungtn Wangchuk(Scientist, SC WHO country Office, Nepal) for support, guiding and facilitation and Ms Sarmistha for organizing through all process and facilitation

Contents

Abbreviation

AFB	Acid fast Bacili
M&S	Monitoring and supervision
MTB	Mycobacterium Tuberculosis
NTC	National TB Center
NTP	National TB Program
PMDT	Programmatic Management of DR TB
PN	Peripheral neuropathy
SEAR	South-East Asia Region (of WHO)
SLD	Second-line anti-TB drugs
SOPs	Standard operating procedures
TA	Technical assistance
TB	Tuberculosis
TWG-TB	Technical Working Group on TB
WHO,CO	World Health Organization, country Office
XDR-RB	Extensively drug-resistant T B

Background and TORs of Mission

Background;

As a part of annual rGLC mission organized by WHO SEARO, this joint visit with WHO team aim to provide Technical support to Nepal TB center and partners for updating the PMDT guidelines in Baccordance with WHO latest 2019 DR TB Recommendations

TORs;

- Background and existing documents/guidelines review for update needed to align PMDT guidelines with WHO 2019 recommendations
- Facilitate stakeholders brainstorming meeting to discuss draft guidelines
- Facilitate and support group work organized by MoH/NTC , WHO/CO and partners to finalize the draft guidelines
- Debriefing with NTC and stakeholders

Major focus of Mission

The main agenda and objectives of the mission as per TORs were to assist, support and assist NTC in updating the PMDT guidelines and aligning with WHO 2019 recommendations. Therefore, mission did not review other components of the program. This report focuses on the 5 days process description of updating PMDT guidelines, Diagnostic and treatment algorithms and treatment regimens.

Overall Summary

The National Tuberculosis Centre (NTC) is the central body responsible for policy, planning, implementation, monitoring and evaluation of the National TB control Programme (NTP). NTC has established Program Management Unit (PMU) at the central level for overall management of the Global Fund grants. At the Regional level, NTP activities are planned and carried out in coordination and cooperation of the Regional Health Directorate. While, within the district, the basic unit of management for diagnosis and treatment are district hospital and the primary health care centers. Directly Observed Treatment is available at Health Post, Sub Health Post and other health institutions within the district.

Nepal is considered as low TB and MDR TB burden country. Total new Tb cases notified in 2017 are 28489 and retreatment cases notified are 3658. While annually about 350-450 RR/MDR TB cases are notified and figure for 2018 is 420 cases. The proportion of new cases with multidrug-resistant TB (MDR-TB) was 2.2% among new cases and 15.4% among retreatment cases based on DRS survey carried out in 2011/12. TSR for RR/MDR TB is about 70%.

There are two national reference laboratories for TB - NTC laboratory and Genetup with established culture, DST and LPA for first and second-line drugs. There are about 59 G.xpert sites in the country.

Table 1 : Achievement v/s targets in past two years and plans for enrolment in coming years

		2016	2017	2018	2019	2020
Total new cases notified	**Target**	**35171**	**36482**	**38267**	**39159**	**41920**
	Actual	**28928**	**28489**			
Retreatment cases notified	**Target**	**3526**	**3658**	**3837**	**3926**	**4203**
	Actual	**3128**	**3275**			
Estimated MDR-TB cases among notified cases (as per target)		**886**	**919**	**963**	**986**	**1055**
MDR-TB cases enrolled	**Target**	**446**	**545**	**641**	**768**	**962**
	Actual	**386**	**429**	**420**		
XDR TB cases	**Target**	**40**	**49**	**58**	**69**	**87**

Table 2: Status of Priority recommendations of the Previous mission(November 2018):

Recommendation	**Responsible persons/agency**	**Timeline**	**Support required to fulfill the recommendation**	**STATUS**
• Planning meeting of provincial heads/ responsible persons could be organized to discuss TB and MDR-TB planning, and sensitization	NTP/MOH and other relevant ministries	Q1 2019		Completed
• Critical need to disseminate standard diagnostic algorithms to all health facilities including Government, private and NGOs run facilities	NTP	Q1 2019	STC and WHO to support	Completed standard guidelines for DR and DS TB and will be disseminated by Q2)
• Treatment delivery mechanisms need to be relooked to make them simpler, easy to access and efficient	NTP/MOH	Q1 2019	STC and WHO to support	Ongoing/in progress
• Update national guideline to the new guidelines for management of H resistant as well as RR/MDR-TB	NTP	Q1 2019	rGLC and WHO HQ support along with country partners	Completed and in process of finalization and printing

• Strengthening recording and reporting including roll-out of new electronic DHIS II based platform	NTP and GF PMU	Q2 2019		In Progress, Will start
• Patient adherence mechanisms are important and should be enhanced e.g. rehabilitation support	NTP/MOH	Ongoing		Ongoing/in progress
• Streamlining of financial support for patients specifically with new federal structure	NTP/MOH and other ministries	Q2 2019		in progress, Will start in Q2

Table 3: Major recommendations of the Current Mission

Recommendation	Responsibility	Timelines	Support Required
Review of current Recording and Reporting tools, align existing in practice R&R tools with updated guideline and WHO companion 2016 handbook	**NTC**	**End of April 2019**	**WHO team partners**
Post outcome follow up of SSTR and LTRs as a policy at 6 months intervals for two years with recording and reporting	**NTC**	**Q4 2019, should reflect and added in new R7R tools**	**WHO and partners**
Strengthening of Monitoring and Supervision of PMDT by using a standard M&S checklist	**NTC**	**Q 3 2019**	**Developing standard check list**
Enhanced MDR TB case finding, optimize G.xpert utilization, review monthly tests done by each Xpert machine and feedback	**NRL, NTC**	**June 2019**	
Assessment of requirement of	**NRL,NTC**	**May 2019**	

Biomedical engineers and recruitment			
Reduce gap between RR TB diagnosis and enrolment, by linking DS TB centers, Xpert sites and MDR TB treatment centers	**NTC, NRL,**	**Q3 2019**	**implementing partners**
Prevention and retrieval of lost to follow up cases and review quarterly reports and feed back	**NTC, implementing partners**	**Q3 2019**	
Strengthening community based care of MDR TB, gradually decentralize MDR TB Treatment and care by ensuring the quality of care and strict DOT	**NTC and implementing partners**	**Q1 2020**	**WHO and PR**
Carry out a network optimization exercise as part of which the utilization of GX machines can be assessed against the patient health seeking behaviour and the current patient care seeking pathway	**NTC and NRL**	**Q3 2019**	**WHO and implementing partners**
Optimize the Turn around Time of LPA SL V2 results preferably with in one week to quickly modify the STR and LTR1 as per resistance patterns reported	**NRL**	**Q3 2019**	**SNRL,WHO**
Transition from Solid CL/DST to Liquid culture/DST and positively consider this shift in upcoming lab commodities forecasting exercise	**NRL**	**Q1 2020**	**SNRL, WHO**
Carry out drug and Lab forecasting exercise every 6 months rather yearly	**NTC**	**Q2 2019**	**WHO, PR and partners**
aDSM mechanism strengthening(as core PMDT package), carry out appropriate causality	**NTC, WHO**	**Q2-3 2019**	**Technically supporting Partners**

assessment of each SAE reported(develop experience) and reporting to WHO UMC			
Notify the focal person for aDSM from existing team	**NTC**	**Q 2 2019**	**NTC**
Establish National core aDSM committee/CAC with TORs in collaboration with country DRA	**NTC,WHO**	**Q 2, 2019**	**DRA**

Detailed Report:

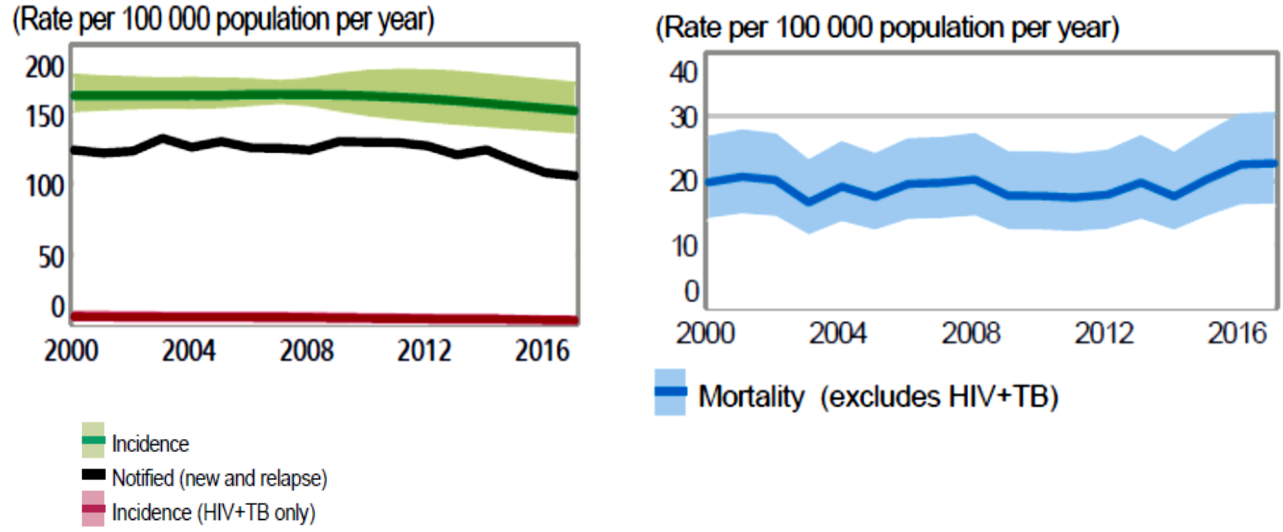
Introduction and Background

Like other countries Nepal NTC is also striving to expand the services of DR TB diagnosis and treatment. Currently there are 20 DR-TB Treatment Centers, 86 DR-TB Treatment ,6 DR-TB Hostel, 1 DR-TB Home, 2 DR-TB Referral Centre, and 1 TB Hospital.

The National Tuberculosis Centre (NTC) is the central body responsible for policy, planning, implementation, monitoring and evaluation of the National TB control Programme (NTP). The National Strategic Plan is a key instrument to appropriately manage and implement NTP. It highlights the overall aim for the control of TB and clearly defines the goal(s) that needs to be reached as well as the Operational Objectives that should be achieved in the next five-year through strengthening TB control efforts. NTC has established Program Management Unit (PMU) at the central level for overall management of the Global Fund grants. This PMU consists of an overall coordination, finance, monitoring & evaluation, sub recipient management, training, procurement and technical sections for private public partnership and advocacy, communication & social mobilization.

At the Regional level, NTP activities are planned and carried out in coordination and cooperation of the Regional Health Directorate. At the Regional level fulltime permanent Regional TB Leprosy Officers are appointed and are responsible for program implementation, training, monitoring & evaluation and supervision of program activities and drug logistics. At the District level, the District Health Officer/District Public Health Officer is responsible for planning and implementation of NTP activities within the district. Within the district, the basic unit of management for diagnosis and treatment are district hospital and the primary health care centres. Directly Observed Treatment is available at Health Post, Sub Health Post and other health institutions within the district.

Figure 1: Estimated trends of incidence and mortality in Nepal (2000-2017)



Overall there has been a decline in TB case notification without a corresponding decline in incidence estimates for the country. There are also concerns regarding rise in estimated mortality among TB cases

Recommendation:

It is understandable in Nepal context the challenges with hard to reach areas and access to diagnosis and treatment. NTC needs to review the issues of accessibility, improving TB services in all sectors and referral of TB and high risk DR TB patients for diagnosis and feed back of results.

As the major objective of the mission was to support in updating guidelines, therefore, no such program performance could have been reviewed. However, during discussions and briefing some important program points have been observed and mentioned here. The report mainly describes areas associated with appropriate guideline revision and its implementation.

Overall Program Performance

Overall the number of cases being diagnosed with RR/MDR-TB have been steadily increasing. The program could enroll 429 and 420 RR TB cases in 2017 and 2018 respectively against its target of 541 and 645 for two recent years.

The major challenge NTC is facing is an increasing gap between those enrolled and those started on treatment was observed for 2017 and 2018 as a minimum of 25% gap has been observed. This may be due to reporting issues from laboratory testing sites (reporting of tests rather than patients) and in some cases initial loss to follow-up of migrants from neighboring countries.

Table 4: Achievement v/s targets in past two years and plans for enrolment in coming years

		2016	2017	2018	2019	2020
Total new cases notified	**Target**	**35171**	**36482**	**38267**	**39159**	**41920**
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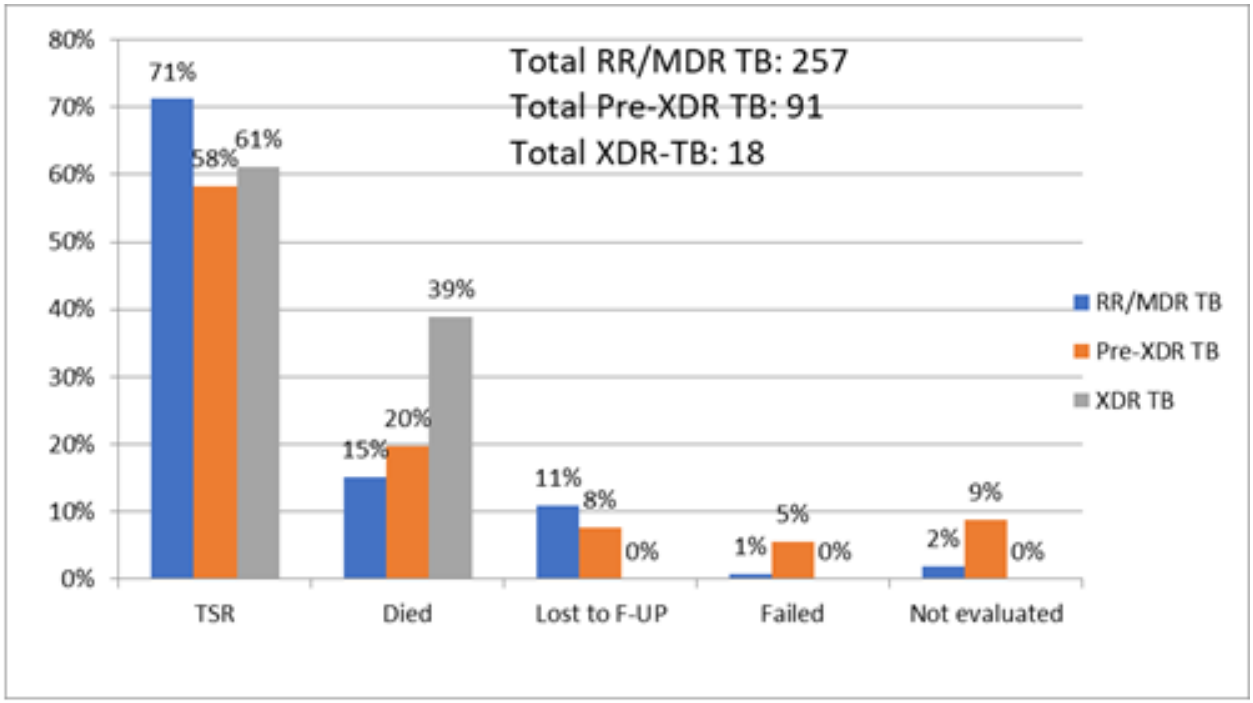
Moreover from the following graph it has been observed that , treatment outcome of RR/MDR TB are about 71%, that is encouraging and efforts can be done to further improve. The lost to follow up is about 19 % among all RR TB cases and this high LFUP has a greater impact on outcomes and further disease

transmission. Likewise, high death rates ranging 15%, 20 to 39% among RR ,Pre XDR and XDR Tb respectively are alarming and there is need to review tis high death rate and may require early case detection and early treatment initiation. The review and analysis of high death rates will provide opportunity to see factors associated with high death(late diagnosis, comorbid conditions, any adverse events etc).

The component of Monitoring and supervision by NTC is indeed there, but should be further reviewed and improved to manage as standardized mechanism by adopting standard M&S checklist.

Graph: Trend of Treatment outcomes of all Types of RR/MDR TB by Cohort



Recommendations:

- Program with support of WHO and partners should review as there is decline in TB case notification without a corresponding decline in incidence estimates for the country and increase in estimated mortality among TB cases
- Reduce gap between RR TB diagnosis and enrolment (25 % gap), by linking DS TB centers, Xpert sites and MDR TB treatment centers and feedback of results
- Carry out a network optimization exercise as part of which the utilization of GX machines can be assessed against the patient health seeking behaviour and the current patient care seeking pathway. The information from the exercise will inform the NTC specifically on:
    - Need for demand-based additional infrastructure (labs and/or equipment)
    - Site wise sample referral design both for public and private facilities
    - Resource needs and optimization to improve access for vulnerable and marginalized populations

- Scaling up effective public and private provider engagement approaches

-
- The network optimization exercise can be further extended to LC and LPA network in order to develop suitable patient / specimen referral mechanisms to these sites as part of network optimization
- Prevention and retrieval of lost to follow up cases(19%) through appropriate and targeted counseling, health education and early side effects detection and management.
- Program should review high death rates among cohorts and address the reasons and define appropriate strategies for early case detection and enrollment in order to prevent mortality.
- Further improvement in Monitoring and Supervision of DR TB program, that incorporates all components of activities by adopting standard M&S checklist

Post treatment outcome follow up and Contact Screening

NTC may occasionally carry out the post treatment outcome follow up in some cases, but not as a policy and without any appropriate recording and reporting. Therefore, data can not be generated on relapse of MDR TB. Likewise, close contact screening of MDR TB patients also happening, but it should be in a systematic way with tools and trainings for staff to carry out this activity and also recording and reporting of close contact screening. It was discussed that as NTC is going to revise R&R tools, so it will be good to incorporate both post treatment outcome and contact screening in patient treatment card by adding sections. By adding these two activities in patient treatment card, it will be easy to monitor.

Recommendation

- Post outcome follow up of SSTR and LTRs as a policy at 6 months intervals for two years with recording and reporting
- Systematic approach for close MDR TB contact screening with proper recording and reporting

aDSM Mechanism

The current aDSM mechanism though functional, but requires further optimization and strengthening. This is extremely important to have stronger aDSM mechanism in place particularly when country is moving forward to adopt new regimen where SAE monitoring applies to all RR/MDR TB patients. For example Linezolid being highly toxic drug, will require close monitoring and either discontinuation or dose reduction as per aDSM protocols to prevent further damage both in case of PN and myelosuppression.

Keeping in view the current status of aDSM in country following is recommended;

Recommendations

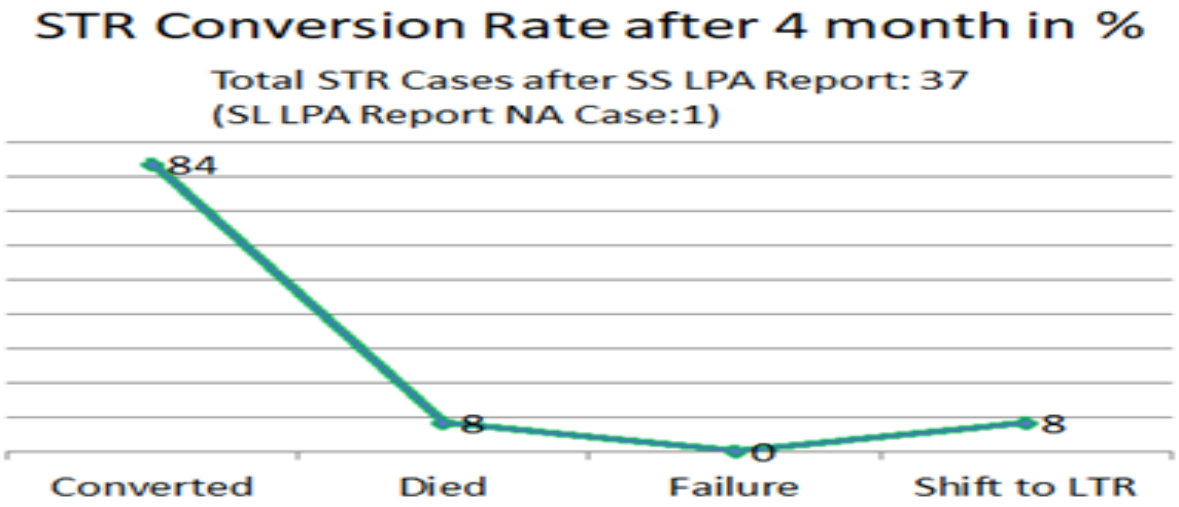
- aDSM mechanism strengthening(as core PMDT package), carry out appropriate causality assessment of each SAE reported(develop experience) and reporting to WHO UMC
- Notify the focal person for aDSM from existing team

- Establish National core aDSM committee/CAC with TORs

Standardized Shorter MDR TB Regimen

Regarding shorter MDR TB regimen, it is currently being implemented as priority treatment in line with patient consent and it was revealed by interim analysis of 37 patients that response to treatment is satisfactory as 84% patients have been converted. However, it was great to observe that no such significant SAEs have been reported. In future, program will continue with standard Am based SSTR as priority treatment regimen and where patients are not eligible for SSTR will be offered all oral longer regimen. Moreover, so far program has no plan to go for modified SST under OR.

The graph below is showing preliminary data about conversion rate among STR cohort.



Updating PMDT Guidelines

Background

The National TB Center, Nepal last updated PMDT guidelines in 2016 and incorporated all WHO recommendations of 2016 and modified diagnostic and treatment algorithms and regimens accordingly.

These PMDT 2016 guidelines were shared to update and make changes to align with WHO 2019 recommendations. Therefore, the work to update guidelines begun 4 weeks before the mission arrival in Nepal so that an updated baseline document should be available to incorporate.

A consultative workshop of 4 days was held to work together and revise guidelines update and incorporate changes.

Process of Guidelines update

As per agenda during the current mission WHO country office and NTC managed a workshop of the writing group consisting of representatives from the NTC and partners (Annex 1). The process included:

- The workshop started with sensitisation of the participants on the recent changes in WHO guidelines 2019 on management of DR-TB including the evidence behind the new recommendations.
- The revised diagnostic and treatment algorithm and proposed options of treatment regimens were presented to NTC and partners

- The participants were divided into four thematic groups.
    - ***Group 1: Case finding and laboratory aspects***
        - Key Definitions
        - Case finding strategy including children, high risk groups and adopting universal DST
        - Laboratory network and Diagnostic algorithm , diagnostic tools
        - Specimen collection and transportation
    - ***Group 2: Treatment strategies and regimens***
        - Pre-treatment evaluation
        - Principles of treatment and Treatment strategies for DR-TB
        - RR/MDR TB regimen construction and types of treatment regimens including adults and children
        - Treatment of DR-TB in Special Situations
        - aDSM mechanisms and management of minor to major adverse effects and events
    - ***Group 3: Treatment support***
        - Treatment delivery & adherence
        - Treatment support including social support, incentives and Counselling
    - ***Group 4: Monitoring and evaluation and others***
        - DR-TB indicators and Tools for R&R
        - Recording, reporting and supervision
        - Infection Control
        - Procurement and supply chain and drug forecasting

- As the guidelines of 2016 were already updated with comments and each group reviewed respective sections in the current guidelines and made changes, incorporated based on the decisions taken by the NTC in line with WHO recent recommendations.
- Every day during the workshop discussions were made on various question arising and to clear any confusions and to make clarity between groups. Points which required discussion with the larger group were raised, addressed and responded by consultants during this time.
- On day three the Technical working group members joined the workshop and major section of discussion of almost half day was spent to get agreement particularly on RR/MDR TB diagnostic and treatment algorithm and proposed options of treatment regimens. This was an essential and much needed activity and all the point of views from NTC manager and TWG members were addressed and incorporated/adopted where all reached to agreement.
- After 4 successful days of workshop as per agenda, on day 5, the TWG meeting was held in WHO country office to debrief NTC and TWG and to get endorsement of all updated

guidelines including RR/MDR TB diagnostic and treatment algorithm, regimens and changes. Likewise, during debriefing, recommendations were made and agreed by NTC.

- The updated guidelines and all updated changes were endorsed by NTC and TWG

Key discussion and decision points:

- Previously NTC was using separate algorithms for diagnosis and treatment but now only one diagnostic and treatment algorithm has been designed that addresses all elements of RR/MDR TB diagnosis, G.xpert results interpretation, using FL LPA and SL LPA and then choosing options of treatment as SSTR, LR 1, LR 2 as per eligibility criteria and DST results.
- Keeping in view the need to test for INH resistance, the need for testing FL LPA has been incorporated and G.xpert results with Rif sensitive in retreatment TB cases and non-converters will be tested by FL LPA to exclude INH resistance and also CI/DST if required.

- The NTC intends to implement universal DST in a phase manner across the country based on the availability and accessibility to the Xpert test. The criteria for G.xpert testing has been expanded in new diagnostic and treatment algorithm.
- The standardised Shorter Treatment Regimen (SSTR) will be the 1st option to treat RR/MDR TB patients as per baseline eligibility criteria and patient doctor mutual agreement by shared based decision.
- Kanamycin will be replaced by Amikacin.
- Patients will be started on SSTR, SL LPA test sent and if Resistance to Fluoroquinolones (FQ) and second line injectables will be shifted to LR2
- Patients on SSTR, if develop any SAE and SSTR can not be continued will be shifted to LR1
- Those ineligible for the SSTR will be treated with either LR1 or LR2

The following all oral regimen(LR1) will be initiated if non- eligible for SSTR

	Resistance Pattern and background History	Regimen	Comments
LR1	Standard longer RR/MDR TB Regimen for adults and children 6 yrs and above Non-eligible for STR and for those whose FQ results unknown/ awaited/sensitive	Bdq(6), 18 Lfx,Lzd,Cfz,Z	*1. In case of toxicity or need to decrease or substitute Lzd with Cs refer to aDSM relevant section* *2. If Lzd is well tolerated, should be continued throughout the treatment duration*

However, in patients with FQ resistance/risk of FQ resistance/XDR TB will be started on following regimen(LR2);

LR2	RR TB with risk of FQ resistance/ FQ resistance at baseline (Pre-XDR) and XDR TB	Bdq (12),18Lzd, Cfz, Cs,Z	*1. High dose Lfx or Mfx can be added once resistance level to FQs are known* *2. In cases with intolerance/toxicity to Lzd, stopping Lzd, replacing with Dlm may be a suitable option.* *3. Close and careful monitoring with combination of three cardiotoxic drugs (Bdq, Cfz,Dlm)*

The updated guidelines also include the diagnosis and management of Hr TB and similar has been reflected in DS TB updated guidelines. If G.xpert test result in retreatment of DS TB or non converters is T

and TI(in TI G.xpert will be repeated to exclude RRTB)then FL LPA will done(in smear -ve cases need for CL/DST may arise) and if Hr is reported SL LPA will also be done to exclude FQ resistance. In Hr TB cases with FQ sensitive the regimen will be 6 Lfx, (H)RZE.

For paediatric MDR TB management, the specific information has been added in diagnosis and treatment chapter for children. In addition, the regimens have been designed and are part of MDR TB management in children as guiding principle about using Dlm or Bdq in specific age groups.

The aDSM chapter has been revised and updated to cover all elements of identification, recording and reporting of SAEs and management options, particularly focused on Bdq, Dlm and Lzd related toxicities along with grading of SAEs. The annexures have been added to diagnose Peripheral neuropathy and to detect QTcF interval prolongation and manage as per aDSM protocols.

The recording and reporting tools for RR/MR TB in use were not well in line with WHO 2016 recommendations, it was briefly discussed and agreed that all tools will be reviewed and adopted as per WHO 2016 recommendations.

The elements of Monitoring and supervision were discussed in detail and its need in terms of adopting new all oral highly effective regimens and strengthening the case holding. As after having such regimens in place the component of M&S should be strengthened. For this purpose the standardised M&S checklist has been shared and is part of updated guidelines as a standard tool of monitoring.

Next steps/Plan of Actions

- Review and finalize Draft updated version of National DR TB management guideline along with Recording and Reporting Tools
- Drug and Lab commodities forecasting and procurement of other required equipment as per need assessment
- Taking on board all stakeholders and partners about transition to oral RR/MDR TB regimens and Transition/implementation plan
- Printing of guideline,
- Development of Training modules based on updated guideline for various cadre of staff with support of technical working group and if needed supported by consultant
- TOT and case cade trainings for all cadre of staff
- Monitoring and supervision

Annexures:

Annex 1: Agenda

Program Agenda: Dr TB Guideline Develoepment (8th-12th April 2019)				
DAY 1				
	Time	**Topics**	**Facilitator**	**Remarks**
	10-.30 11 AM	Registration	ALL Participants	
	11:00-11:15 AM	Opening remarks	Director NTC	
	11:15-11.30AM	Objectives of the Program	Dr Lungten Wangchuk-WHO	
	11:30-11:40AM	Short remarks for GTB-HQ	Dr Medea- WHO-HQ	
	11:40-11:45 AM	Short remark and expereince from pakisthan	Dr Asif-Consulatnt	
	11:45-12:20 AM	**Group PHOTO and TEA BREAK**		
	12:20-1:00 PM	Present proposed changes to the current guideline	Dr Asif and Dr Medea	
	1:00-2:00 PM	**LUNCH**		
	2:00-4:00 PM (Tea break in between)	**Discussion on the New Proposed Regimen and agreement of the most applicable for Nepal**	Rationale by Drs Meda and Asif	Discussion all

DAY 2 &3 (9th-10th April)				
	9:00- 11:00	Groups write their sections	all groups	
	11:00- 11.30	**TEA BREAK**		
	11:30-1:00 PM	Continue writing	All groups	
	1:00-2:00 PM	**LUNCH**		
	2:00-3:00 PM	Continue writing	All groups	
	3.00-3.30 PM	**TEA BREAK**		
	3:30- 5:30 PM	DISSCUSSION and feedback of each section in plenary		All group chaired by Dr Tinkari, Dr Lungten and consulatnts (Drs Asif & Medea)
	Day 4 (11th April)			
	9:00- 11:00 AM	Groups revsie their sections as per last discussion and feedback		All group
	11:00- 11.30 AM	**TEA BREAK**		
	11:30-1:00 PM	Continue revision and hand over to Dr Asif and Meda for final synthesis		All gropus
	1:00-2:00 PM	**LUNCH**		
	2:00-3:30 PM (Tea break in between)	Dr Asif and Dr Medea synthesis of the final Draft of the guideline (group can help if required)		
	3.00-3.30 PM	**TEA BREAK**		

	3:30-4.30 PM	Dr Asif and Dr Meda present the final draft key areas particularly the new regimen and key areas of update to Director NTC and the Group	
	4.:30- 4:45 PM	**CLOSING**	Director NTC
	4:45PM	**TRAVEL BACK TO KATHMANDU**	ALL
Day 5 (12th April-FRIDAY)			
	11:00 AM- 2:00 PM	**TWG as per agenda and endorse the DS and DR-TB Guideline at WHO Conference Room**	**Chaired by NTC Director**

Annex 2: Technical working Groups for Guideline Update

List of participants: DR TB Guidelines Update (8-11 April 2019), Dhulikhel Kavre					
SN	**Name of Participants**	**Designation**	**Organization**	**Contact No**	**Email Address**
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